

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
MARSHALL DIVISION

JANIS GRAHAM and JOHN GRAHAM, §  
§  
Plaintiffs §  
§  
v. § Civil Action No. 2-07-CV-318-LED  
§  
MERCK & CO. INC., § JURY TRIAL DEMANDED  
§  
Defendant. §

**ANSWER AND AFFIRMATIVE DEFENSES OF MERCK & CO., INC.**

Defendant, Merck Co., Inc. ("Merck"), by and through its undersigned attorneys, hereby answers the Complaint. Merck denies all allegations set forth in the Complaint except to the extent such allegations are specifically admitted below:

**I. PARTIES**

1. Merck denies each and every allegation of Paragraph 1, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.
2. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 2.
3. Merck admits that it is a corporation organized under the laws of the State of New Jersey with its principal place of business in New Jersey. Except as expressly admitted herein, Merck denies the remaining allegations of Paragraph 3. Merck further admits that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

## II. GENERAL BACKGROUND AND OVERVIEW OF CLAIMS

4. Merck denies each and every allegation of Paragraph 4, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information and admits that Plaintiffs bring this action seeking damages, but denies that there is any legal or factual basis for same.

5. Merck denies each and every allegation of Paragraph 5, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 5 inconsistent with that prescribing information and respectfully refers the Court to the Physician's Desk Reference ("PDR") for FOSAMAX® for its actual language and full text.

6. Merck denies each and every allegation of Paragraph 6.

7. Merck denies each and every allegation of Paragraph 7.

8. Merck denies each and every allegation of Paragraph 8.

9. Merck denies each and every allegation of Paragraph 9.

10. Merck denies each and every allegation of Paragraph 10.

11. Merck denies each and every allegation of Paragraph 11.

12. Merck denies each and every allegation of Paragraph 12.

13. Merck denies each and every allegation of Paragraph 13, except that Merck admits that Plaintiffs are seeking damages, but denies that there is any legal or factual basis for same.

## III. JURISDICTION AND VENUE

14. Merck is without knowledge as to the allegations in Paragraph 14, but for jurisdictional purposes only, admits that the Plaintiffs seek in excess of \$75,000.

15. The allegations in Paragraph 15 are conclusions of law to which no response is required. To the extent that a response is deemed necessary, Merck is without knowledge or information sufficient to form a belief as to these allegations, except that Merck admits that it is a corporation organized under the laws of the State of New Jersey with its principal place of business in New Jersey, and admits, for jurisdictional purposes only, that the amount in controversy exceeds \$75,000.00.

16. The allegations in Paragraph 16 are conclusions of law to which no response is required. To the extent that a response is deemed necessary, the allegations are denied.

17. Merck denies each and every allegation of Paragraph 17, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® in accordance with its approved prescribing information.

#### **IV. FACTUAL BACKGROUND REGARDING PLAINTIFF**

18. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 18.

19. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 19.

20. Merck denies each and every allegation of Paragraph 20.

21. Merck denies each and every allegation of Paragraph 21.

22. Merck denies each and every allegation of Paragraph 22.

23. Merck denies each and every allegation of Paragraph 23.

#### **V. FACTUAL BACKGROUND REGARDING DEFENDANT AND FOSAMAX**

24. Merck denies each and every allegation of Paragraph 24, except that Merck admits that it sought and, in 1995, first obtained FDA approval to manufacture and market

FOSAMAX® 10 mg and FOSAMAX® 40 mg tablets, a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 24 inconsistent with that prescribing information.

25. Merck admits only that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 25 inconsistent with that prescribing information. Merck also refers the Court to the prescribing information for Aredia and Zometa, and denies any allegations in Paragraph 25 with respect to Aredia and Zometa inconsistent with that prescribing information.

26. Merck admits only that some bisphosphonates contain nitrogen and some do not and that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 26 inconsistent with that prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Merck also refers the Court to the prescribing information for Aredia, Bondronat, Didronel, Bonefos, Loron, and Skelid, and denies any allegations in Paragraph 26 with respect to Aredia, Bondronat, Didronel, Bonefos, Loron, and Skelid inconsistent with that prescribing information. Merck denies the remaining allegations of Paragraph 26.

27. Merck denies each and every allegation of Paragraph 27.

28. Merck denies each and every allegation of Paragraph 28.

29. Merck denies each and every allegation of Paragraph 29.

30. Merck denies each and every allegation of Paragraph 30.

31. Merck denies each and every allegation of Paragraph 31.

32. Merck denies each and every allegation of Paragraph 32.

33. Merck denies each and every allegation of Paragraph 33.
34. Merck denies each and every allegation of Paragraph 34, except that Merck admits that the FDA drafted an "ODS Postmarketing Safety Review," but respectfully refers the Court to said document for its actual language and full text.
35. Merck denies each and every allegation of Paragraph 35.
36. Merck denies each and every allegation of Paragraph 36.
37. Merck denies each and every allegation of Paragraph 37.
38. Merck denies each and every allegation of Paragraph 38, except that Merck admits that FOSAMAX® product sales in 2006 amounted to approximately \$3.13 billion.
39. Merck denies each and every allegation of Paragraph 39.
40. Merck denies each and every allegation of Paragraph 40.
41. Merck denies each and every allegation of Paragraph 41.
42. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 42.
43. Merck denies each and every allegation of Paragraph 43.
44. Merck denies each and every allegation of Paragraph 44, except that Merck admits that FOSAMAX® product sales in 2005 amounted to approximately \$3.19 billion.

## **VI. EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS**

45. Merck denies each and every allegation of Paragraph 45.
46. Merck denies each and every allegation of Paragraph 46.
47. Merck denies each and every allegation of Paragraph 47.
48. Merck denies each and every allegation of Paragraph 48.

**VII. CLAIMS FOR RELIEF**  
**A. FIRST CLAIM FOR RELIEF: NEGLIGENCE**

49. Merck repleads its answers to Paragraphs 1 through and including 48, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

50. The allegations in Paragraph 50 are conclusions of law to which no response is required. To the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

51. Merck denies each and every allegation of Paragraph 51.

52. Merck denies each and every allegation of Paragraph 52, including each and every allegation contained in subparts (a) through (n).

53. Merck denies each and every allegation of Paragraph 53.

54. Merck denies each and every allegation of Paragraph 54.

55. Merck denies each and every allegation of Paragraph 55.

In response to the final un-numbered paragraph of this section of Plaintiffs' Original Complaint, Merck admits that Plaintiffs are seeking damages, but denies that there is any legal or factual basis for same.

**B. SECOND CLAIM FOR RELIEF: STRICT LIABILITY – FAILURE TO WARN**

56. Merck repleads its answers to Paragraphs 1 through and including 55, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

57. Merck denies each and every allegation of Paragraph 57, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

58. Merck denies each and every allegation of Paragraph 58.

59. Merck denies each and every allegation of Paragraph 59.

60. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 60.

61. Merck denies each and every allegation of Paragraph 61.

62. Merck denies each and every allegation of Paragraph 62.

63. Merck denies each and every allegation of Paragraph 63.

64. Merck denies each and every allegation of Paragraph 64.

65. Merck denies each and every allegation of Paragraph 65.

66. Merck denies each and every allegation of Paragraph 66.

67. Merck denies each and every allegation of Paragraph 67.

In response to the final un-numbered paragraph of this section of Plaintiffs' Original Complaint, Merck admits that Plaintiffs are seeking damages, but denies that there is any legal or factual basis for same.

### **C. THIRD CLAIM FOR RELIEF: STRICT LIABILITY – DEFECTIVE DESIGN**

68. Merck repleads its answers to Paragraphs 1 through and including 67, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

69. Merck denies each and every allegation of Paragraph 69<sup>1</sup>, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

70. Merck denies each and every allegation of Paragraph 70, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information, and Merck states that it is without knowledge as to the condition of the FOSAMAX® Plaintiff alleges she consumed.

71. Merck denies each and every allegation of Paragraph 71.

72. Merck denies each and every allegation of Paragraph 72.

73. Merck denies each and every allegation of Paragraph 73.

74. Merck denies each and every allegation of Paragraph 74.

In response to the final un-numbered paragraph of this section of Plaintiffs' Original Complaint, Merck admits that Plaintiffs are seeking damages, but denies that there is any legal or factual basis for same.

#### **D. FOURTH CLAIM FOR RELIEF: BREACH OF EXPRESS WARRANTY**

75. Merck repleads its answers to Paragraphs 1 through and including 74, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

76. Merck denies each and every allegation of Paragraph 76, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

77. Merck denies each and every allegation of Paragraph 77.

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<sup>1</sup> Plaintiffs' Original Complaint erroneously numbered this paragraph as 79.

78. Merck denies each and every allegation of Paragraph 78.
79. Merck denies each and every allegation of Paragraph 79.
80. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 80.
81. Merck denies each and every allegation of Paragraph 81.

In response to the final un-numbered paragraph of this section of Plaintiffs' Original Complaint, Merck admits that Plaintiffs are seeking damages, but denies that there is any legal or factual basis for same.

#### **E. FIFTH CLAIM FOR RELIEF: BREACH OF IMPLIED WARRANTY**

82. Merck repleads its answers to Paragraphs 1 through and including 81, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.
83. Merck denies each and every allegation of Paragraph 83, except that Merck admits that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.
84. Merck denies each and every allegation of Paragraph 84, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.
85. Merck denies each and every allegation of Paragraph 85.
86. Merck denies each and every allegation of Paragraph 86.
87. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 87.

88. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 88.

89. Merck denies each and every allegation of Paragraph 89.

In response to the final un-numbered paragraph of this section of Plaintiffs' Original Complaint, Merck admits that Plaintiffs are seeking damages, but denies that there is any legal or factual basis for same.

**F. SIXTH CLAIM FOR RELIEF: FRAUD**

90. Merck repleads its answers to Paragraphs 1 through and including 89, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

91. Merck denies each and every allegation of Paragraph 91.

92. Merck denies each and every allegation of Paragraph 92.

93. Merck denies each and every allegation of Paragraph 93.

94. Merck denies each and every allegation of Paragraph 94.

95. Merck denies each and every allegation of Paragraph 95.

96. Merck denies each and every allegation of Paragraph 96.

97. Merck denies each and every allegation of Paragraph 97.

In response to the final un-numbered paragraph of this section of Plaintiffs' Original Complaint, Merck admits that Plaintiffs are seeking damages, but denies that Plaintiffs are entitled to any of the damages or relief requested.

**G. SEVENTH CLAIM FOR RELIEF: FRAUDULENT MISREPRESENTATION  
AND/OR CONCEALMENT**

98. Merck repleads its answers to Paragraphs 1 through and including 97, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

99. Merck denies each and every allegation of Paragraph 99, including each and every allegation contained in subparts (a) and (b).

**H. EIGHTH CLAIM FOR RELIEF: NEGLIGENCE PER SE**

100. Merck repleads its answers to Paragraphs 1 through and including 99, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

101. Merck admits the allegation in Paragraph 101.

102. Merck denies each and every allegation of Paragraph 102.

103. The allegations in Paragraph 103 are conclusions of law to which no response is required. To the extent that a response is deemed necessary, Merck denies each and every allegation of Paragraph 103.

104. The allegations in Paragraph 104 are conclusions of law to which no response is required. To the extent that a response is deemed necessary, Merck denies each and every allegation of Paragraph 104.

105. Merck denies each and every allegation of Paragraph 105.

106. Merck denies each and every allegation of Paragraph 106.

**I. NINTH CLAIM FOR RELIEF: UNJUST ENRICHMENT**

107. Merck repleads its answers to Paragraphs 1 through and including 106, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

108. Merck denies each and every allegation of Paragraph 108, except that Merck admits that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

109. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 109.

110. Merck denies each and every allegation of Paragraph 110.

111. Merck denies each and every allegation of Paragraph 111.

112. Merck denies each and every allegation of Paragraph 112.

In response to the final un-numbered paragraph of this section of Plaintiffs' Original Complaint, Merck admits that Plaintiffs are seeking damages, but denies that there is any legal or factual basis for same.

**J. TENTH CLAIM FOR RELIEF: LOSS OF CONSORTIUM**

113. Merck repleads its answers to Paragraphs 1 through and including 112, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

114. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 114.

115. Merck denies each and every allegation of Paragraph 115.

116. Merck denies each and every allegation of Paragraph 116.

117. Merck admits that Plaintiffs are seeking damages in Paragraph 117, but denies that there is any legal or factual basis for same.

## **VII. DEMAND FOR JURY TRIAL**

118. Merck admits that Plaintiffs have demanded a jury trial.

## **VIII. PRAYER FOR RELIEF**

119. Merck admits that Plaintiffs are seeking damages, but denies that there is any legal or factual basis for same.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

### **AFFIRMATIVE DEFENSES**

Discovery and investigation may reveal that any one or more of the following affirmative defenses should be available to Merck in this matter. Merck, therefore, asserts said affirmative defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these affirmative defenses as it may deem appropriate. Further, Merck reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Merck demands strict proof of all claims and allegations contained in Plaintiffs' Complaint that Merck has not expressly admitted. Further answering and by way of additional defense, Merck states as follows:

### **FIRST AFFIRMATIVE DEFENSE**

Each and every claim asserted or raised in the complaint is barred by the applicable statute of limitations and is otherwise untimely.

**SECOND AFFIRMATIVE DEFENSE**

The complaint fails to state a claim upon which relief can be granted.

**THIRD AFFIRMATIVE DEFENSE**

Each and every claim asserted or raised in the complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

**FOURTH AFFIRMATIVE DEFENSE**

If Plaintiffs have sustained injuries or losses as alleged in the complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

**FIFTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiffs assert claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

**SIXTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiffs assert claims based upon an alleged failure by Merck to warn Plaintiffs directly of alleged dangers associated with the use of FOSAMAX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

**SEVENTH AFFIRMATIVE DEFENSE**

Other persons or entities who are not parties to this suit were guilty of negligence which was the sole proximate cause of, or a contributing cause to, the damages alleged in the complaint. Merck anticipates more specific information regarding the identity and potential

liability of these non-parties will be developed during discovery. Accordingly, any damages awarded should be apportioned.

**EIGHTH AFFIRMATIVE DEFENSE**

The injuries and damages, if any, sustained by the Plaintiffs resulted in whole or in part from their own comparative negligence and any damages recovered should be reduced accordingly.

**NINTH AFFIRMATIVE DEFENSE**

If Plaintiffs have sustained injuries or losses as alleged in the complaint, such injuries or losses were only sustained after Plaintiffs knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or another manufacturer.

**TENTH AFFIRMATIVE DEFENSE**

If Plaintiffs have sustained injuries or losses as alleged in the complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

**ELEVENTH AFFIRMATIVE DEFENSE**

If Plaintiffs have sustained injuries or losses as alleged in the complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiffs' misuse or abuse of FOSAMAX®.

**TWELFTH AFFIRMATIVE DEFENSE**

If Plaintiffs have sustained injuries or losses as alleged in the complaint, such injuries or losses resulted from Plaintiffs' pre-existing and/or unrelated medical, genetic and/or

environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

**THIRTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims for breach of warranty are also barred for lack of timely notice of breach and/or lack of privity.

**FOURTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

**FIFTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

**SIXTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused the injuries asserted in the complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiffs seek punitive damages, such claim is barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

**NINETEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

**TWENTIETH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

**TWENTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

**TWENTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

**TWENTY-THIRD AFFIRMATIVE DEFENSE**

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

**TWENTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or in part by failure to mitigate damages.

**TWENTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

**TWENTY-SIXTH AFFIRMATIVE DEFENSE**

With respect to each and every cause of action, Plaintiffs are not entitled to recovery for strict liability because Plaintiffs cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiffs' claims to a negligence cause of action.

**TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

All activities of Merck as alleged in the complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiffs' claims pertaining to unfair or deceptive practices are barred.

**TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

With respect to each and every cause of action, Plaintiffs are not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

**TWENTY-NINTH AFFIRMATIVE DEFENSE**

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States and Texas Constitutions.

**THIRTIETH AFFIRMATIVE DEFENSE**

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiffs' claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

**THIRTY-FIRST AFFIRMATIVE DEFENSE**

At all times relevant herein, any product which is the subject matter of this action processed and distributed by Merck in any state in the United States was processed and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

**THIRTY-SECOND AFFIRMATIVE DEFENSE**

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

**THIRTY-THIRD AFFIRMATIVE DEFENSE**

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

**THIRTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiffs have not sustained an ascertainable loss of property or money.

**THIRTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiffs have not suffered any actual injury or damages.

**THIRTY-SIXTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred under the doctrine of economic loss.

**THIRTY-SEVENTH AFFIRMATIVE DEFENSE**

This case is more appropriately brought in a different venue as defined in 28 U.S.C.

§1404(a).

**THIRTY-EIGHTH AFFIRMATIVE DEFENSE**

This case is subject to dismissal and/or transfer to another venue pursuant to 28 U.S.C.

§1406(a).

**THIRTY-NINTH AFFIRMATIVE DEFENSE**

This case is subject to dismissal or stay on the grounds of *forum non conveniens*.

**FORTIETH AFFIRMATIVE DEFENSE**

Merck is entitled to a set-off or reduction in any damages which may be awarded to the Plaintiffs for any amounts received from collateral sources.

**FORTY-FIRST AFFIRMATIVE DEFENSE**

To the extent that Plaintiffs asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

**FORTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiffs' claims of fraud are not pleaded with the required particularity.

**FORTY-THIRD AFFIRMATIVE DEFENSE**

If Plaintiffs sustained the injuries and damages alleged in the Complaint, such injuries resulted, in whole or in part, from the culpable conduct and negligence of Plaintiffs and/or of third parties, not from any negligence or breach of duty by Merck. If judgment is rendered in Plaintiffs' favor, the amount of such judgment must be reduced pursuant to the Proportionate Responsibility Statute § 33.001, et seq. of the Texas Civil Practice & Remedies Code.

**FORTY-FOURTH AFFIRMATIVE DEFENSE**

Merck is unaware at this time of any settlements by any alleged joint tortfeasor. In the event any settlement is or has been made by any alleged joint tortfeasor, however, then Merck is entitled to a full credit, offset, pro rata reduction, or percentage reduction, based on the percentage of fault attributable to each settling party, person, or other entity herein, and Merck makes known to the other parties and to the court that it will avail itself of its rights under §§ 33.012 et seq. of the Texas Civil Practice & Remedies Code.

**FORTY-FIFTH AFFIRMATIVE DEFENSE**

Merck fully asserts § 82.001 and § 82.007 of the Texas Civil Practice and Remedies Code and states that all of Plaintiffs' claims are barred under those sections.

**FORTY-SIXTH AFFIRMATIVE DEFENSE**

To the extent Plaintiffs are seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action.

**FORTY-SEVENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims of fraud are barred by reason of Plaintiffs' failure to allege the circumstances constituting fraud with particularity, as required under both state and federal rules.

**FORTY-EIGHTH AFFIRMATIVE DEFENSE**

Any claims for exemplary damages are limited by Section 41.008 of the Texas Civil Practice and Remedies Code to two times the amount of actual damages or \$200,000, whichever is greater. Merck asserts all other defenses and limitations on punitive damages contained in Chapter 41 of the Texas Civil Practice and Remedies Code.

**FORTY-NINTH AFFIRMATIVE DEFENSE**

Any claim for punitive damages against Merck cannot be sustained, because an award of punitive damages under Texas law without proof of every element beyond a reasonable doubt would violate Merck's rights under Amendments IV, V, VI and XIV of the United States Constitution and under Sections 9, 10, 14 and 19 of Article I of the Texas Constitution.

**FIFTIETH AFFIRMATIVE DEFENSE**

Unless Merck's liability for punitive damages and the appropriate amount of punitive damages are each required to be established by clear and convincing evidence under Texas law, any awards of punitive damages would violate Merck's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by Section 19 of Article I of the Texas Constitution.

**FIFTY-FIRST AFFIRMATIVE DEFENSE**

Any claims for punitive damages against Merck cannot be sustained, because any award of punitive damages under Texas law without bifurcating the trial as to all punitive damages issues would violate Merck's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by Section 19 of Article I of the Texas Constitution.

**FIFTY-SECOND AFFIRMATIVE DEFENSE**

Any claim for punitive damages against Merck cannot be sustained, because an award of punitive damages under Texas law subject to no pre-determined limit, either a maximum multiple of compensatory damages or a maximum amount, on the amount of punitive damages that a jury may impose would violate Merck's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by Section 19 of Article I of the Texas Constitution.

**FIFTY-EIGHTH AFFIRMATIVE DEFENSE**

Any claims for punitive damages against Merck cannot be sustained, because an award of punitive damages under Texas law by a jury that:

- (1) is not provided any standard of sufficient clarity for determining the appropriateness, or the appropriate size of any punitive damages award;
- (2) is not instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment;
- (3) is not expressly prohibited from awarding punitive damages or determining the amount of an award of punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics;
- (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; or
- (5) is not subject to judicial review on the basis of objective standards, would violate Merck's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by Section 19 of Article I of the Texas Constitution.

**FIFTY-NINTH AFFIRMATIVE DEFENSE**

Any claims for punitive damages against Merck cannot be sustained, because an award of punitive damages under Texas law for the purpose of compensating Plaintiffs for elements of damages not otherwise recognized by Texas law would violate Merck's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by Section 19 of Article I of the Texas Constitution.

**SIXTIETH AFFIRMATIVE DEFENSE**

Merck asserts that the determination of the amount of punitive damages, if any, should be bifurcated from the remaining issues pursuant to *Transportation Ins. Co. v. Moriel*, 879 S.W.2d 10 (Tex. 1994).

**SIXTY-FIRST AFFIRMATIVE DEFENSE**

The imposition of punitive damages violates the open courts provision of the Texas Constitution.

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In so much as the complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

**JURY DEMAND**

Merck demands a trial by jury as to all issues so triable.

Respectfully submitted,  
BAKER BOTTS L.L.P.

/s/ Richard L. Josephson  
by permission /s/ W. Zachary Hughes  
Richard L. Josephson  
Federal ID No. 04614  
State Bar No. 11031500  
910 Louisiana  
Houston, Texas 77002  
Telephone: (713) 229-1234  
Telecopy: (713) 229-1522  
ATTORNEY-IN-CHARGE FOR  
MERCK & CO., INC.

OF COUNSEL:

W. Zachary Hughes  
Federal I.D. No. 30097  
State Bar No. 24032441  
BAKER BOTTS L.L.P.  
910 Louisiana  
Houston, Texas 77002  
Telephone: (713) 229-1234  
Telecopy: (713) 229-1522

**CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the foregoing was sent to all known counsel of record via the Court's electronic filing system, on this 5th day of September, 2007.

W. Mark Lanier  
Kenneth S. Soh  
The Lanier Law Firm, PC  
6810 FM 1960 West  
Houston, Texas 77069

/s/ W. Zachary Hughes  
W. Zachary Hughes